

JUN 13 2005

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June 13, 2005

Date

PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	James Arthur Hoffmann)
Serial No.	:	10/072,540)
Filed	:	February 8, 2002) Group Art Unit: 1614
For	:	GLP-1 Formulations) Examiner: Delacroix-Muirheid
Docket No.	:	X-11368A)

COMMUNICATION

Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

Sir:

On 6 June 2005, Applicant filed a Request for Continued Examination under 37 C.F.R. § 1.114 of U.S. Serial No. 10/072,540. In response to the Final Rejection (Paper No. 122804) dated January 11, 2005, Applicant also submitted a response, an amended IDS form 1449, and a Declaration under 37 C.F.R. § 1.131 from the inventor and Applicant, James Arthur Hoffmann. In addition, a petition for a two-month extension of time under 37 C.F.R. § 1.136 was also included in the mailing.

It has come to my attention that Exhibit A (that was to accompany the Declaration of Applicant James Hoffmann) was inadvertently omitted from this case.

Serial No. 10/072,540

Applicant respectfully requests that the Examiner enter the Exhibit A into the 6 June 2005 Declaration. If for any reason, the Examiner feels a telephone conversation would be helpful, the Examiner is urged to call me.

Respectfully submitted,



Gregory A. Cox
Attorney for Applicant
Registration No. 47,504
Phone: 317-276-0280

Eli Lilly and Company
Patent Division/GAC
Lilly Corporate Center
Indianapolis, Indiana 46285

June 13, 2005

Project No. E2B

Book No. LIA

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Procedure: Fresh 10% excipients that allows V8-GC-1 (7.57) off to rotatory power in 500ml beakers with 3115 mg/ml m-cresol at 25-27.8°C RT and 4°C.

Procedure: 100 mg (7.57) of V8-GC-1 was prepared at 10mg/ml in 10ml of 10% m-cresol in 100ml round bottom beaker. 10ml of 10% m-cresol was added to the 100ml with 3115 mg/ml m-cresol. The power at 100mg/ml is off.

For each sample taken to 500ml of V8-GC-1 solution was added the equivalent of 300 mg fed at RT. 15.8ml of the m-cresol solution was added. Mix and store at RT 2-4 hr.

S8-51

Sample

Bulbifex

W/ m-cresol
Stay Clear
at RT?

W	10ml Tween 40	OK	Yes
W	10ml Tween 80	OK	Yes To Page No. 7
W			
W			

Project No. 638

Book No. 15A

Title: U.S. GEL/Increased Transparency + Additives

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From Page No.

Procedure used:

All 4 samples that remained clear at RT during the day (24 hr) were checked again after an overnight in the refrigerator (4°C).

Two more samples were made up later in the day:

T=21

Sample

Additive

Very Clear

and RT

X

1% Tween 40

OK

Almost

Y

1% Tween 80

OK

Not

Sample Y had a lot of flocculation and aggregation right away, while sample X had only a trace of flocculation at RT.

After overnight at 4°C all solutions that had remained clear at RT were checked. None was totally clear, although sample W was almost clear.

Results: several additives in the U.S. GEL/Increased Transparency formulation help maintain clarity at RT.

and 2% Tween at these levels though, none of the additives was able to keep the flocculation clear at 4°C overnight in the refrigerator.

On re-warming to RT all samples re-clearified quickly.

The aggregation phenomenon at 4°C (related to hardness effects) appears to be reversible.

Conclusion: several additives

2% Tween 40 or 80) improved clarity at 4°C of U.S. GEL/

In formulations with increased core glycerin at 20%, especially at ambient temperature.

Witnessed & Understood by me,

Date

Inventor by: James A. Thompson

Recorded by: [Signature]